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10/509,595	09/29/2004	Kaoru Asano	Q83447	3089

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EXAMINER
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WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



***ELECTION/RESTRICTIONS***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Group I:** Claims 1-10, 12, and 14-20 drawn to a method for examining a gene comprising detecting a variation in nucleic acid bases and predicting any future development of glaucoma using said variation as an index, classified in class 702, subclass 019. If this Group is elected, then the below summarized specie election is also required.

**Group II:** Claim 11 drawn to a primer function-possessing oligonucleotide, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is also required.

**Group III:** Claim 13 drawn to an examination reagent or examination reagent kit, classified in class 536, subclass 23.1.

The inventions are distinct and divergent, each from the other because of the following reasons:

Inventions of Groups [II and III] and Group I are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inventions of Groups II and III could be

Art Unit: 1631

used in any number of other molecular techniques which use primers and examination reagents, such as PCR and microarray kits, respectively.

The examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. Thus, the search for these groups together would present an undue search burden as they are directed to methods and products that are generally distinct and separate.

### ***SPECIE ELECTION REQUIREMENT***

This application contains claims directed to patentably distinct and divergent species of the claimed inventions. If Group I or II is elected, the applicant is further required to make the following specie elections for purposes of examination:

#### **Specie A**

Species of positions within a gene region are cited in claim 1, 10, , 11, 18, and 20, which are distinct gene coding regions (i.e. glaucoma-related and/or an upstream region) requiring detection assays with chemically distinct materials that are generally separately published. This documents undue search burden if searched together. Thus applicants are required to select one type of gene region from the following list:

- i. A position within a gene region containing a glaucoma-related gene coding region.
- ii. A position within a gene region containing a glaucoma-related upstream region.
- iii. A position within a gene region containing both a glaucoma-related gene coding region and a glaucoma-related upstream region.

Art Unit: 1631

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic to the above species.

### **Specie B**

Species of variations in nucleic acid base sequence are cited in claims 5-8, which are distinct nucleic acid mutations requiring detection assays with chemically distinct materials that are generally separately published. This documents undue search burden if all nucleic acid mutations are searched together. Thus applicants are required to select one substitution at one position in the nucleic acid base sequence represented by SEQ ID No: 1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-4, 11, 14-16, 18, and 20 are generic to the above species.

### ***Sequence Election Requirement Applicable to Groups II and III***

In addition, Groups II and III as detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR

Art Unit: 1631

1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct and divergent, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the

Art Unit: 1631

evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

Art Unit: 1631

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*12/15/05*